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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,962	03/22/2001	Ljerka Kunst	4810-58563	1208

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

13

DATE MAILED: 08/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/787,962

Applicant(s)

KUNST ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14, 24-31, 33, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 and 39 is/are allowed.
- 6) ☒ Claim(s) 1-14, 24-31 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Applicant's election without traverse of Group I, claims 1-14, 24-31 and 33 in Paper No. 12 is acknowledged.

The amendment filed May 12, 2003 has been entered.

Claims 1, 2, 4-9, 11-14 and 31 are newly amended.

Claims 38-39 are newly submitted.

Claims 1-14, 24-31, 33 and 38-39 are examined in the present office action.

### ***Specification***

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The disclosure is objected to because of the following informalities: The specification fails to reference parent applications in the first paragraph.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-14, and claims 24-31, 33 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14 are indefinite in the recitation of KCS2, since this abbreviation can refer to something other than a long chain fatty acid biosynthetic enzyme, such as to a transcription factor, as evidenced by Huang et al (Genetics 141 (4): 1275, 1995, the Abstract). In addition, at part b) of claim 1, KCS2 is referred to without reference to a particular sequence. It is unclear what an Arabidopsis KCS2 means by just stating the name. Therefore, the metes and bounds of the claimed invention are unclear, and the specification fails to define or clarify the use of KCS2 regarding what sequences would be encompassed by this term.

Claims 1 and 8 are also indefinite in stating that the “nucleic acid coding sequence is derived from an Arabidopsis KCS2 . . .” since it is unclear what it means to be “derived from” or what changes in the nucleic acid may result.

Claim 1 is further indefinite in the recitation of “heterologous”, since it is unclear what said nucleic acid is heterologous to.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-14, 24-31 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. The claims are drawn to any Arabidopsis KCS2 that will hybridize under stringent conditions or is at least 70% identical to nucleotides 1046-2509 of SEQ ID NO: 1 or to any plant very long chain fatty acid condensing enzyme that has an amino acid sequence that is at least 70% identical to an Arabidopsis KCS2 amino acid sequence or to any nucleic acid derived from an Arabidopsis KCS2 sequence that encodes a very long chains fatty acid condensing enzyme. However, the only KCS2 coding sequence provided in the specification is nucleotides 1046-2509 of SEQ ID NO: 1. It is unclear what other sequences would confer the same functional activity. The specification does not describe the structural features that would define the claimed genus.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

7. Claims 1-14, 24-31 and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the Arabidopsis KCS2 of nucleotides 1046-2509 of SEQ ID NO: 1, does not reasonably provide enablement for any Arabidopsis KCS2 that will hybridize under stringent conditions or is at least 70% identical to nucleotides 1046-2509 of

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SEQ ID NO: 1 or to any plant very long chain fatty acid condensing enzyme that has an amino acid sequence that is at least 70% identical to an Arabidopsis KCS2 amino acid sequence or to any nucleic acid derived from an Arabidopsis KCS2 sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The specification teaches that the Arabidopsis KCS2 coding sequence of nucleotides 1046-2509 of SEQ ID NO: 1 encodes a plant very long chain fatty acid condensing enzyme. However, the specification does not disclose any other sequences that encode a protein with said functional activity.

While one may be able to identify other sequences that are similar, sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions" (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that "there are numerous cases in which proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that "most homologs must have different molecular and cellular functions" (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12,

10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a particular activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known to encode fatty acid a plant very long chain fatty acid condensing enzyme activity, one cannot conclude that these other sequences also encode enzymes having plant very long chain fatty acid condensing enzyme activity. In addition, De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that “on many occasions desired goals have been impossible to achieve” (see the last paragraph on page 228N). Therefore, both the identification of other genes encoding plant very long chain fatty acid condensing enzyme activity, and the modification of plant lipid composition by transforming a plant with said gene or a portion of said gene are highly unpredictable.

Thus, given the unpredictability of identifying sequences that exhibit plant very long chain fatty acid condensing enzyme activity and modifying the lipid composition of a plant; the lack of guidance in the specification for identifying and characterizing sequences that exhibit

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fatty acid a plant very long chain fatty acid condensing enzyme activity; the lack of working examples of fatty acid a plant very long chain fatty acid condensing enzyme activity coding sequences, and the lack of working examples of similar sequences that encode proteins having the same activity; and the breadth of the claims, and use of said genes to modify a fatty acid; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

***Claim Rejections - 35 USC § 101***

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to plants and a seed of a plant. However, it is unclear that the plant would differ from a plant in which the recited sequence is naturally occurring. In addition, the claim does not specify that the seed comprises the nucleic acid sequence that was transformed into the plant. Due to Mendelian inheritance the seed may not comprise said sequence. In addition, the claim does not indicate that the seed would have any characteristics that would distinguish it from seeds produced in nature.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:



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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5, 8-12, 24-31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Metz et al (WO 95/15387 in the IDS).

The claims are drawn to an Arabidopsis KCS2 that will hybridize under stringent conditions or is at least 70% identical to nucleotides 1046-2509 of SEQ ID NO: 1 or to any plant very long chain fatty acid condensing enzyme that has an amino acid sequence that is at least 70% identical to an Arabidopsis KCS2 amino acid sequence or to any nucleic acid derived from an Arabidopsis KCS2 sequence and a method of transforming a plant and a plant or cell transformed with said sequence.

Metz et al teach an Arabidopsis sequence that codes for a plant very long chain fatty acid condensing enzyme and falls within the scope of the claims. Metz et al also teach transformed plants and plant cells comprising said sequence and modifying fatty acid composition in the transformed plant (see pages 67-69, for example).

Claims 38-39 are allowed, given that the prior art does not teach or suggest the specific nucleic acid sequence of nucleotides 1046-2509 of SEQ ID NO: 1.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is 703-308-1794. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Elizabeth F. McElwain  
Primary Examiner  
Art Unit 1638

EFM  
July 31, 2003